

Appl. No. 10/706,103
Atty. Docket No. 9118M2
Amdt. dated February 14, 2006
Reply to Office Action of November 18, 2005
Customer No. 27752

REMARKS

Claim Status

Claims 1 - 17 are pending in the present application. No additional claims fee is believed to be due.

Claims 1, 12, 13, 14, and 16 have been amended to more specifically characterize the invention. Support for the amendment in Claim 14 is found at page 7, paragraph 3 of the specification. Support for the amendment in Claim 16 is found at pages 6-7 of the specification.

Rejection Under 35 USC §112, First Paragraph

The Office Action states that the term "safe and effective" in claims 1, 12, 13, 14, and 16 is a relative term which renders the claims indefinite. Applicants assert that "safe and effective" amount is defined on page 4 of the specification and one having ordinary skill in the art would know what amount of an ingredient would be safe and effective. However, to advance prosecution, Applicants have removed the term "safe and effective" from the claims.

The Office Action states that the term "particulate retentive agent" relates to an extremely large number of possible products and has no distinct meaning in the art. Applicants assert that a particulate retentive agent is clearly defined in the specification on the end of page 10. Applicants have provided a meaning for the term particulate retentive agent through descriptions and examples in the specification. Applicants have also required that the particulate retentive agent have a water solubility of less than about 1g/30g at 25C.

Double Patenting Rejection

Claims 1-17 are provisionally rejected under the doctrine of double patenting over claims 1-35 of Application No. 10/706,104. Applicants have submitted a terminal disclaimer to overcome the rejection.

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Rejection Under 35 USC §102 Over Lawlor

Claims 1, 2, 3, 5, 6-10, and 12-16 are rejected under 35 USC 102(a) and (e) as being anticipated by Lawlor US 6,706,256 B2 (hereinafter referred to as "Lawlor"). Before discussing Lawlor, Applicants would like to summarize the present invention for the Examiner. In Claim 1, the present invention relates to a non-cariogenic, non-effervescent, chewable, dentifrice solid unit dose compositions comprising a particulate retentive agent, an oral care active, a surfactant, and a buffer. The particulate retentive agent is present in amount of from about 30% to about 65% by weight and has a water solubility of less than about 1g/30g. The composition has a Retention Index of about 1 to about 4.

Lawlor discloses an oral care composition containing an effective amount of an antibacterial seed or pulp extract from the Citrus or Vitis plan family. The oral care compositions are formulated for use in the oral cavity and intended to treat or prevent oral malodour. Lawlor discloses that the oral composition can be a confectionery composition, such as a chewing gum, hard and low boiled candy carrier, pressed tablets and the like. Lawlor's examples include 12 chewing gums, 2 lozenge, 2 compressed mints, 2 mouthrinses, and 2 dentifrice compositions. None of these compositions are intended to or disclosed as having a Retentive Index of from about 1 to about 4. A chewing gum is chewed, a lozenge and mint are sucked, a mouthrinse is swished, and dentifrices are brushed on the teeth and rinsed. There is no disclosure or suggestion that the compositions in Lawlor should be chewed for the purpose of being retained on the tooth surface and measuring a Retention Index of from about 1 to about 4. In the ordinary and normal use of a confectionary, the products are formulated so that they do not retain on a tooth surface as that is typically viewed as an aesthetic negative from a user. Therefore, Lawlor does not anticipate the present invention as Lawlor does not contain all elements of the present invention as there are no teachings or suggestions that any confectionary composition **during its normal use** will result in the composition being retained on the tooth surface from about 1 minute to about 60 minutes as is required in a Retention Index of from about 1 to about 4.

As the Office Action states, Lawlor does disclose hydrogenated starch and hydroxymethyl cellulose. However, these two materials would not anticipate the present

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invention as they are not particulate retentive agents with a water solubility of less than about 1g/30g at 25C.

For a claim to be anticipated, each and every element of the claim must be present in the prior art reference. It is not sufficient that a person following the disclosure sometimes obtain the result set forth in the [claim], it must invariably happen. *Standard Oil Co. v. Montedison, S.p.A.*, 664 F.2d 356, 372 (3rd Cir. 1981). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F3d 743, (Fed Cir., 1999). Therefore, Lawlor does not anticipate the present invention as there is no specific disclosure to develop a composition with a Retentive Index of from about 1 to about 4 nor is there any disclosure to use a composition so that a Retentive Index of about 1 to about 4 would result.

Rejection Under 35 USC §103(a)

Claims 1-11 have been rejected under 35 USC §103(a) as being unpatentable over Lawlor and Blue US 4,978,521 (hereinafter referred to as Blue) in view of Aberg et al., WO 88/10110 (hereinafter referred to as Aberg). Claims 13-17 are rejected under 35 USC §103(a) as being unpatentable over Blue, Aberg in further view of Lawlor and Witt US 6,350,438 (hereinafter referred to as Witt). Applicants respectfully traverse this rejection. The Lawlor reference is discussed above. As Applicants have pointed out, there is no teaching or suggestion in Lawlor to produce or use a composition resulting a Retentive Index of from about 1 to about 4.

Aberg discloses a tooth cleaning and fluoridating tablet. "The tooth cleaning tablet of the invention is designed to form a self-foaming paste when chewed in the mouth. The paste is then swished around the mouth and through the teeth for about 1 to 2 minutes (preferably at least 2 minutes) and then swallowed. This cleans and polishes the tooth surfaces by mechanical action ..." (page 5, second paragraph) Aberg states the purpose is to use mechanical action to clean and polish the tooth surface. Therefore, **Aberg teach away from the present invention** which a Retention Index of about 1 to 4. A composition retained on the tooth surface would not be able to provide the mechanical action taught in Aberg.

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Aberg discloses a carbon dioxide producing composition comprise less than about 50% by weight, and preferably less than 25% by weight. Aberg states this is to provide a paste rather than thin slurry. Although Aberg suggests limiting the amount of carbon dioxide producing part of the composition to less than 50%, and preferably less than 25%. **Aberg does not teach or suggest a non-effervescent paste.** Aberg simply states that it is not desired to have a thin slurry which would not be as effective for mechanical cleaning. Applicants assert that Aberg does not teach or suggest a non effervescent paste. Aberg simply discloses to control the amount of carbon dioxide produced so that the dentifrice slurry will still provide cleaning.

Blue teaches a color coded flavored dentifrice toothpowder. Witt discloses a oral care composition containing chlorite. Neither Blue nor Witt does not teach or suggest a Retion Index of from about 1 to about 4. Neither Blue nor Witt teach or suggest a non-effervscent oral composition.

The Office Action states that "One of ordinary skill in the art would have combined the teachings of Lawlor and Blue with that of Aberg to make an oral dentifrice tablet that is **non-effervescent, chewable, leave a substantial amount of the composition on the tooth surface** because the active agent for a composition of a tooth tablet are well known within the art." (page 8) Neither Lawlor, Blue nor Aberg teach or suggest forming a chewable, solid unit dose composition which provides a Retention Index of about 1 to 4. No reference teaches or suggests forming a non-effervescent composition. Lawlor's objective is to treat malodour in the oral cavity and it is not to leave a substantial amount of the composition on the tooth surface. The objective of Aberg is to clean and polish the tooth surfaces by mechanical action and it is not to leave a substantial amount of the composition on the tooth surface. Therefore, one having ordinary skill in the art would not have been motivated by the disclosure in Lawlor and Blue in view of Aberg to develop a non-effervescent chewable, solid unit dose composition providing a Retention Index of about 1 to about 4.

The Office Action also states that one or ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art and expect a successful result in doing so, because the aim of preventive dentistry has been to improve the efficacy of oral hygiene and overall health in mammals (p.8) and because the drugs used have previously been used for the same function claimed by applicant (p.9). Applicants

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assert that one having ordinary skill in the art would not have been motivated to combine Lawlor, Blue, and Aberg. Lawlor's objective is to treat malodour by a antibacterial seed or plant extract from the Citrus or Vitis plant family. The majority of Lawlor's examples are for a chewing gum. Aberg's objective is to clean and polish the teeth and provide fluoride. Aberg's teaching is for a paste that cleans and polishes the teeth which teaches away from a Retention Index of from about 1 to about 4. Blue's teaching is for a color coded flavored dentifrice toothpowder. There are large numbers of oral care reference in the prior art and there is no motivation to combine a reference preferably for a chewing gum for treating malodour with a tablet to produce a non-effervescent composition with a Retentive index of from about 1 to about 4. Therefore, one having ordinary skill in the art would not have been motivated by the teachings of the above cited art to develop the present invention.

The Office Action also states on page 11 that "It is obvious for the composition of oral care to stay within the oral cavity for 2 minutes, if the oral care is in the form of a lozenges or a slow dissolving tablet." Applicants assert that the present invention requires that the oral care dentifrice composition is chewable and that it has a Retention Index of from about 1 to about 4. The Retention Index requires that the composition is deposited on a molar/premolar surface, not simply that the composition remain in the oral cavity. Therefore, one having ordinary skill in the art would not have been motivated by the teachings of the above cited art to develop the present invention.

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Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-17 is respectfully requested.

Respectfully submitted,

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Date: February 14, 2006
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